

ADOLESCENT BIPOLAR DEPRESSION RESEARCH STUDY

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04.15.09
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Dr. Michael Plopper at Sharp Mesa Vista Clinical Research Center, Examining Symbyax® for Use in Pediatric Patients with Depressive Episodes Due to Bipolar I Disorder

A Phase IV Clinical Research Study Now Enrolling Patients

Dr. Plopper at Sharp Mesa Vista Clinical Research Center, Working to Determine if Symbyax® May Be Efficacious and Safe for Pediatric Patients with Bipolar I Disorder

Investigators across the United States are enrolling participants in a clinical trial called the Adolescent Bipolar Depression Research Study. This is a Phase IV, multicenter, randomized, double-blind, placebo-controlled, parallel-group study clinical research study to assess the efficacy and safety of olanzapine and fluoxetine combination (Symbyax®) versus placebo in patients ages 10 to 17 in the treatment of major depressive episodes associated with bipolar I disorder. Dr. Plopper at Sharp Mesa Vista Clinical Research Center is leading this effort locally and is currently enrolling patients into the clinical research study.

Symbyax® is approved by the Food and Drug Association (FDA) for adult patients who suffer from depressive episodes associated with bipolar I disorder. Although the exact mechanism of action is unknown, Symbyax® has been shown to affect the three neurotransmitters that are important in the treatment of bipolar depression: serotonin, dopamine, and norepinephrine.

The lack of available treatment options for pediatric patients has resulted in the off-label use of many different bipolar medications to help adolescents with bipolar I disorder find relief from their depressive episodes. While research has been conducted to study the effects of many of these bipolar medications, Symbyax® has yet to be formally studied in the pediatric population.

To this end, the Adolescent Bipolar Depression Research Study is investigating whether Symbyax® is safe and effective for adolescents with depressive episodes associated with bipolar I disorder. It is hoped that the data gathered from this study may lead to expanded knowledge about treatment options for adolescents with bipolar I disorder.

Approximately 300 patients will be randomized into the study to assess the superiority of Symbyax® compared with placebo, as measured by the mean change in Children's Depression Rating Scale-Revised (CDRS-R). Following a 2- to 45-day screening period, qualified patients will be randomized and will enter an 8-week double-blind treatment period in which they will be randomly assigned to receive once-daily oral dosing with the investigational drug or placebo (2:1).

APPROVED

By Sharp Healthcare Institutional Review Board at 10:13 am, Apr 02, 2009

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Everyone who participates in the Adolescent Bipolar Depression Research Study will receive (at no cost):

- Access to close assessment and monitoring by a physician who is interested in depressive episodes due to bipolar I disorder.
- Study-related visits and evaluations.
- Study drug – either the investigational drug or a placebo (2:1).

To be considered for participation in this clinical research study, patients must be:

- Ages 10 to 17 years (male or female), AND
- Diagnosed with bipolar I disorder and are experiencing symptoms of depression , **OR**
- In the opinion of the study doctor, currently experiencing symptoms of depression that may be indicative of bipolar I disorder.

Learn More

Dr. Plopper at Sharp Mesa Vista Clinical Research Center is seeking participants and can be contacted by phone at 858-694-8311 or by e-mailing the study coordinator, Jana Horowitz, PsyD at jana.horowitz@sharp.com. Jana is also available to meet in person to answer any questions that you may have, and to share additional information about this study.

Thank you very much for your attention.

The Adolescent Bipolar Depression Research Study

www.AboutThisStudy.com/bipolar